REMARKS

Claims 1, 2, 4-7 and 17 are all the claims pending in the application.

I. Claims 1, 2, 4-7 and 17 are Patentable Under 35 U.S.C. § 101

At page 2 of the Office Action, the Office rejects claims 1, 2, 4-7 and 17 under 35 U.S.C. § 101 as allegedly lacking utility.

Applicants disagree and traverse the rejection.

The law is a specification which contains a disclosure of utility must be taken as sufficient to satisfy the utility requirement of § 101 unless there is a reason for one skilled in the art to question the objective truth of the statement of utility. *In re Langer* (503 F.2d at 1391) [Emphasis added] *In re Jolles (*628 F.2d 1322), *In re Irons* (340 F.2d 974), *In re Sichert* (566 F.2d 1154, 1159). In *In re Brana* (51 F.3d 1560, Fed. Cir. 1995), the Federal Circuit explicitly adopted the *Langer* standard as articulated in *In re Marzocchi* (439 F.2d 220), which indicates that the Office must presume that a statement of utility made by an applicant is true. See *In re Langer*; *In re Malachowski* (530 F.2d 1402); *In re Brana*. Evidence of utility includes arguments, reasoning, or additional new evidence.

The Commissioner instructs that Office personnel must focus on and be receptive to assertions made by Applicants that the invention is "useful" for a particular reason. The PTO "Utility Examination Guidelines" are applicable to determinations of utility.[1] The PTO "Utility Examination Guidelines" at page 32 state that "a "well-established utility" is specific, substantial, and credible utility which can be implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. As stated by

[1] *In re Fisher*, 421 F.3d 1365, 1372.

the Federal Circuit, "[t]o violate [35 U.S.C.] 101 the claimed [invention] must be totally incapable of achieving a useful result."[2] Even "[a] small degree of utility is sufficient."[3]

Applicants have clearly established for the record the nexus between C1 protein (i.e., SEQ ID NO: 1) and enhanced expression in nerve cells subjected to ER stress. Applicants have further established, as the Examiner admits, that the expression of C1 is enhanced in rat primary nerve cells that have been stimulated with J3 amyloid. Office Action, pages 2-4. Applicants have clearly established that C1 promotes cell death in SK-N-AS cells (human neuroblastoma) and that C1 inhibits secretion of A1340 and A1342 in IMR-32 cells (human neuroblastoma). Office Action, pages 2-4. Furthermore, Applicants have pointed out to the Office that the state of art at the time of invention has established such connection between Alzheimer's disease and Aβ. See, Seubert *et al.* The experimental results of decreased secretion of Aβ from cell transfected with C1 proves the specific, substantial and credible utility of the claimed protein to diagnose and treat Alzheimer's disease. Further, Siemers et al. [...], and Fleisher et al. [...] report clinical trails for the compound LY450139, having Aβ secretion inhibitory activity,as a therapeutic agent for Alzheimer's disease.

The Office continues to improperly question Applicants' evidence of utility even though the law makes clear that if a single asserted utility is credible, in view of the record or the nature of the invention, a lack of utility rejection is not appropriate. This is however, precisely what has been done - the Office assumes that Applicants' asserted utility is false, based on the generalizations in the technical field and other speculation. Applicants have asserted a particular

[2] *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992). (emphasis added).

[3] *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 (8th Cir. 1980).

utility, and that assertion cannot simply be dismissed by the Office under current law even when there may be reason to believe that the assertion is not entirely accurate. The Office's allegations that "there is no disclosure that the instant polypeptides or polynucleotides can be used as a marker for AD, or that the polypeptide of SEQ ID NO:1 can be used for therapeutic purposes to treat AD" refers to evidence that is not required by statute. In fact, rigorous correlations are not necessary. *See Rey-Bellet v. Englehardt*, 493 F.2d 1380. Evidence is sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. The Office thus failed to establish a prima facie case of lack of utility and failed to accord proper weight to the utility evidence asserted by the Applicants.

A person of ordinary skill in the art would immediately appreciate why Applicants' invention is useful because of the properties disclosed. Given the nexus between C1 protein and enhanced expression in nerve cells subjected to endoplasmic reticulum stress; enhanced expression of C1 in nerve cells stimulated with J3 amyloid; C1 promotion of cell death in human neuroblastoma; and C1 inhibition of secretion of A1340 and A1342, one having ordinary skill in the art would appreciate a relationship between C1 and Aβ secretion processes. In addition, based on the state of the art, a connection between Alzheimer's disease and Aβ (Seubert *et al.)* and the clinical trails for compound LY450139 (having the Aβ secretion inhibitory activity) as a therapeutic agent for Alzheimer's disease (Siemers et al. and Fleisher et al.) make apparent a well established utility for Applicants' invention. Rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, given the facts are improper and should not be imposed. *In re Folkers*, 344 F.2d 970.

Based upon the law, and for at least the following reasons discussed below, there is sufficient evidence that the claimed protein has a well-established or specific, substantial, and

credible utility for, *inter alia*, screening compounds that inhibit the apoptosis promoting activities of C1.

Withdrawal of the lack of utility rejection is kindly requested.

II. Claims 1, 2, 4-7 and 17 are Enabled Under 35 U.S.C. § 112, First Paragraph

In paragraph 7, on page 5 of the Office Action, the Office rejects claims 1, 2, 4-7 and 17 under 35 U.S.C. § 112, first paragraph.

Specifically, the Examiner states that the rejection under 35 U.S.C. § 112, first paragraph is contingent on the rejection under 35 U.S.C. § 101, addressed above. Thus, for the reasons discussed above, in Section I, the rejection should be withdrawn.

Withdrawal of the lack of enablement rejection is kindly requested.

III. Claim 17 Adequately Defines Applicants' Invention under 35 U.S.C. § 112, Second Paragraph

In paragraph 9, on page 5 of the Office Action, the Office maintains the rejection of claim 17 under 35 U.S.C. § 112, second paragraph.

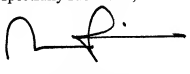
The Office's rejection is premised on the allegation that the C1 protein is not sufficiently characterized (citing to the reasoning in Section 5 of the Office Action). Thus, for the reasons discussed above, in Sections I and II, the rejection should be withdrawn.

Withdrawal of the rejection is kindly requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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